REMARKS

Applicants submit this response to the Office Action of May 16, 2007. Claims 1-19, 27, and 29-61 are cancelled without prejudice. Claim 20 is amended as discussed below. Dependent claims 21-23, and 25 are amended to conform to claim 20 as amended. Thus, claims 20-26 and 28 remain present under consideration. No new matter has been added by this amendment.

Applicants thank the Examiner for the courtesy of a personal interview with the undersigned representative in May 2007. At the interview, the Examiner indicated that an Office Action would be issued, and this response addresses the detailed comments in the Office Action of May 16, 2007. While applicants respectfully disagree with portions of Examiner's arguments, the presently amended claims are believed to be fully responsive to all of Examiner's concerns. The presently amended claims do not indicate any accession to Examiner's positions and applicants reserve the right to pursue cancelled subject matter in a continuing application.

Before addressing the substance of the Office Action, applicants wish to request withdrawal of the finality of the Office Action. Although the box was checked indicating that the Office Action is final, the Office Action failed to include the proper paragraph as provided for in the M.P.E.P.:

> 7.39 Action Is Final
>
> THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
>
> A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Because the paragraph was not included in the May 16, 2007 Office Action, applicants were not given the notice regarding deadlines, and the simple checking of a box could have been a clerical error, not the Examiner's decision. Applicants therefore

strongly urge that the Examiner withdraw the finality. This is especially requested under the circumstances of the present amendment cancelling most of the claims and significantly narrowing the issues which the Examiner will be considering prior to issuing the next communication, which applicants submit should be a Notice of Allowance.

As introduction to the remarks on the substance of the Office Action, applicants respectfully submit that the presently pending claims are now in condition for allowance. A summary of applicants' support for this statement as well traversal of outstanding rejections is provided below.

1. With regard to the rejection of prior claims under 35 U.S.C. §101, the applicants respectfully submit that all such rejected claims have now been cancelled and the remaining claims 20-26, and 28 were not subject to rejection under 35 U.S.C. §101.

2. With regard to the rejection under 35 U.S.C. §112 as insufficiently enabled, applicants submit that the presently amended claims address all of the Examiner's concerns. In support of this and in response to the Examiner's arguments, applicants submit the following specific responses.

a. The Examiner asserted that there would be an unpredictable amount of experimentation required to practice the claimed invention. Applicants submit that the presently amended claims are so specific as to require only common practice of the art. In further support of this statement, the Examiner's attention is also drawn to the previously presented expert affidavits of Drs. Lesser and Myers. The present claims specify a clear method that would be appreciated by those skilled in the art to determine whether each candidate gene contains functional variants that make the respective gene a target for therapeutic intervention.

Applicants request that the Examiner give serious consideration to the expert affidavits, and address the substance of the affidavits. Applicants note that the Federal Circuit has recently ruled that evidence submitted by applicants in rebuttal to a rejection, such as submitted declarations, must be given "meaningful consideration." *In re Sullivan*, p. 12, No. 08.405,454 (Fed. Cir., Aug. 29, 2007). In vacating and remanding the Appeals' Board's decision for failing to properly consider the declarations submitted as evidence in rebuttal to the rejection, the Federal Circuit stated that, "when an

applicant puts forth relevant rebuttal evidence, as it did here, the Board must consider such evidence." *Id.* The court went on to say that the rejection cannot be maintained if competent evidence rebuts the rejection, and that "[b]y failing to consider the submitted evidence, the Board thus committed error." Applicants submit that the previously submitted affidavits have not been given "meaningful consideration," as rebuttal evidence to the rejection at hand, in light of the statement made therein relating to enablement of the claimed invention at the time that the application was filed.

b. The Examiner asserted that the "disclosure does not provide guidance... that result in identification of a drug target for 'any' biological condition". Applicants respectfully disagree with this statement and reiterate that the statistically significant correlation of *functional* allele variants with the ARU group, as is described in the specification (e.g. page 12) and now incorporated in the presently amended claims, constitutes identification of a drug target. As the Examiner will appreciate, a "drug target" as known to those skilled in the art is any gene or gene product, to which a therapeutic is addressed, irrespective of the particular therapeutic approach used to address the target.

Applicants stress that it is important to consider the fundamental difference between a disease gene causative mutation and a protective mutation described in the present disclosure. A protective mutation (that is a functional mutation specifically associated with the ARU group) is one in which the effect of the mutation is desirable. This is in direct opposition to the classical disease causing mutation which can be determined to cause the disease. The critical distinction is that the *effect* of a protective mutation can be mimicked therapeutically to treat a disease whereas the disease causing mutation does not directly provide therapeutic strategy.

Applicants submit that on page 8 of the Office Action, the Examiner has concluded erroneously that because a disease gene mutation does not lead to a drug target, that the present method has a high degree of unpredictability. In fact, the present method does not rely on disease gene mutation identification but rather protective mutation identification – an essential difference. Because of the distinction between protective mutations of the present method and disease gene mutations as described above, the Examiner's conclusion of high unpredictability does not follow.

Instead, the identification of the protective mutation concurrently identifies the gene carrying the protective as a drug target.

c. Additionally, applicants respectfully traverse the Examiner's concerns regarding the use of the term "biological condition" by amendment of the present claims without prejudice to use the term "disease" instead. Applicants submit that this claim language is aligned with the present method of identifying a target to treat the disease. Support for the amendment is found throughout the specification, including the following statement at page 8, lines 23-25: "It should be noted that the term 'biological condition' refers to a biological state, disease, physiological condition or the like. These terms may be used interchangeably throughout the application."

d. Applicants submit that the instant amendments also make the present claims sufficiently clear and that these claims are enabled by the disclosure so as to allow a skilled artisan to apply the claimed methods to any disease for which suspect candidate genes are available.

e. The Examiner asserted that the disclosure does not provide any example of wherein a drug target was identified. While the disclosure was prophetic on this point, the procedure outlined in the disclosure was followed by applicants after filing of the present application and this led to the discovery of the drug target, OAS1 in a hepatitis C development program. This fact was emphasized in the previously presented affidavit of Dr. Iadonato. Therefore, the Examiner's argument that the disclosure does not provide any examples is moot because following the procedure described in the disclosure was successful.

Applicants note that the Federal Circuit has recently ruled that evidence submitted by applicants in rebuttal to a rejection, such as submitted declarations, must be given "meaningful consideration." *In re Sullivan*, p. 12, No. 08.405,454 (Fed. Cir., Aug. 29, 2007). In vacating and remanding the Appeals' Board's decision for failing to properly consider the declarations submitted as evidence in rebuttal to the rejection, the Federal Circuit stated that, "when an applicant puts forth relevant rebuttal evidence, as it did here, the Board must consider such evidence." *Id.* The court went on to say that the rejection cannot be maintained if competent evidence rebuts the rejection, and that "[b]y failing to consider the submitted evidence, the Board thus committed error."

Applicants submit that the previously submitted affidavits have not been given "meaningful consideration," as rebuttal evidence to the rejection at hand, in light of the statement made therein relating to enablement of the claimed invention at the time that the application was filed.

f. The Examiner states that the nature of the invention is complex. While the applicants do not disagree that drug target discovery can be a complex process, it is unclear how this relates to any purported lack of enablement which the Examiner appears to be suggesting. Applicants submit that the Examiner's presumption of complexity in the field makes the fact that applicants were successful in following the disclosed procedure to identify a drug target all that much more supportive of sufficient enablement.

In all other regards, applicants respectfully submit that all other of Examiner's arguments for rejection under 35 U.S.C. §112 are now rendered moot by the presently amended claims. Support for the amendment to recite "disease" has been discussed above in paragraph 2(c). Support for performing tests "in a panel of candidate genes..." is found at least at page 9, lines 21-25. Support for "identifying functional variants..." is found at least at page 9, lines 11-15. Support for "identify one or more statistically significant..." is found at least at page 9, lines 8-16. Support for identifying drug targets is found at least at page 11, lines 5-10, and support for displaying identified target candidate genes to a user is found throughout the description of Figure 1 at page 15, line 3 to page 16, line 8, as well as page 17, lines 1-3. Applicants therefore respectfully request that the Examiner find the present claims in condition for allowance.

Commissioner is hereby authorized to charge the required fees to Deposit Account No. 04-0258. If additional fees are believed necessary, the Commissioner is further authorized to charge any deficiency or credit any overpayment to Deposit Account No. 04-0258.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 757-8122.

Respectfully submitted,
Charles L. Magness
DAVIS WRIGHT TREMAINE LLP

By Melanie K. Kitzan Hartfield #57,397
for Jane E. R. Potter
Registration No. 33,332

Enclosure:
Postcard

1201 Third Avenue, 2200
Seattle, WA 98101-3045
Phone: (206) 622-3150
Facsimile: (206) 757-7700